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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|---------------------------------|
| 09/847,654 | 05/03/2001 | Roderic M. K. Dale | 033995-0143 | 9139 |
| 22852 | 7590 | 03/09/2004 | | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005 | | | | EXAMINER KRISHNAN, GANAPATHY |
| | | | | ART UNIT 1623 PAPER NUMBER |

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/847,654 | DALE ET AL. |
| | Examiner | Art Unit |
| | Ganapathy Krishnan | 1623 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15, 31 and 32 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-4, 6, 8, 11, 13, 31 and 32 is/are rejected.
- 7) Claim(s) 5, 7, 9, 10, 12, 14 and 15 is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-15, 31 and 32 in the response filed December 17, 2003 is acknowledged. The traversal is on the ground(s) that the method of claim 30 and the compositions of claims 1-15, 31 and 32 constitute a single invention because the haloperoxide compositions disclosed in US patent 5510104 cannot be used to practice the method of claim 30, specifically the haloperoxide containing compositions disclosed in US 5510104 require co-administration of a halide compound and as such the haloperoxide compositions cannot be used alone to practice the method as claimed in instant claim 30. This is not found persuasive because instant claim 30 is a method of using the product of the invention for treating a microbial infection and as such can be practiced with a materially different product as in US 5510104, which is drawn to a method of killing or inhibiting (treating) microorganisms.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 6, 10 and 15 are objected to because of the following informalities: In claim 6, in the structures ZO-CH₃CH₂CH₂CH₂-O- and XO-CH₃CH₂CH₂CH₂-O- the CH₃ attached to ZO- and XO- on the left should be changed to a CH₂. Claims 10 and 15 are duplicates. Either claim 15 has to be further limiting or it should be canceled.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15, 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 31 recite the general structure X-Y-Z. There is no chemical core, name or formula recited for X and Z. The term molecule in the claim lacks antecedent basis. It is not clear if the term molecule refers to the blocking agents or the phosphorus-containing moiety or to X-Y-Z as a whole.

Claims 2 and 3 which depend from claim 1 do not further define X and Z.

Claim 4 fails to end in a period. It is unclear where applicant intends for the subject matter claimed to conclude additional text if any.

Claim 6 and 8 recite structures for X and Z with oxygen attached to the right, for the composition according to claim 5. If these structures are to be attached to both sides of the Y component as shown in claim 5, the combination results in a peroxide linkage, that is, the oxygen of the structures recited in claim 6 would be directly attached to the oxygen to the left and right of the end phosphorus atoms in the structure recited in claim 5 resulting in the peroxide link. It is not clear if this is what is intended. The structure recited in claim 10 and those shown on page 13 of the specification do not show a peroxy link. Clarification is required. For the purpose of prosecution the claims are interpreted to mean structures as recited in claim 10. This recitation is also seen in claim 13.

Claims 6 and 13 define what X and Z are but the defined structures in these claims also have X and Z shown in the structures. X and Z cannot be a part of the structures that are used to define X and Z. The claim is unclear.

Claim 11 recites the limitation "carrier" in claim 1. There is insufficient antecedent basis for this limitation in the claim. For the purpose of prosecution the term carrier is interpreted to mean the same as excipient.

Claim 12 recites X and Z in the structure. There is no chemical core, name or formula recited for X and Z. except reciting that X and Z are blocking agents.

Claims that depend from rejected base claims that are unclear/indefinite are also rendered unclear/indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 11, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Chikawa et al (US 5153000).

Chikawa et al, drawn to phosphate containing preparations, teaches compositions comprising phosphates (phosphorus containing moiety) of formula (I) (col. 2, lines 25-30) in which M can be a hydrogen (col. 2, lines 57-58), A is either of groups (i) or (ii) (col. 2, lines 35-44). The Z group can be a mono or polyether group (col. 2, lines 60-67). The phosphate of formula (I) meets the limitations of claim wherein the A and Z groups of formula (I) constitute the end-blocking groups X and Z of the formula in instant claim 1 and claim 31. The phosphates can be made into a composition by mixing with water and other active components like sorbitol (col. 8, lines 40-48). Sorbitol is an excipient (see entry # 8873, page 1490, Merck Index, 12th

edition, 1996). This meets the limitation (b) in claim 1. The phosphate group in formula (I) of Chikawa meets the limitation of instant claim 4 when M is hydrogen. Also, in formula (I) of Chikawa, the two end blocking groups A and Z are different. This meets the limitation of instant claim 3. Another agent in the composition is glycerol (see col. 8, lines 40-46). Glycerol is an emollient, a humectant and a lubricant (see entry 4493, pages 763-764, Merck Index, 12th edition, 1996). This meets the limitations of instant claim 11. Chikawa's composition also preferably contains an alkali metal salt of organic acid like benzoic acid (metal salt of a carboxylic acid). This meets the limitation of claim 32.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by McIntosh et al (US 4908209).

McIntosh et al disclose a biocidal composition comprising a phosphate ester of the general formula shown at col. 10, lines 35. The R and R' groups which constitute the end blocking groups can be same or different and are selected from alkyl, aryl, aralkyl and alkaryl groups (col. 20, lines 25-43) with an inert carrier (excipient). This disclosure of McIntosh et al meets the limitations of claims 1-4.

Conclusion

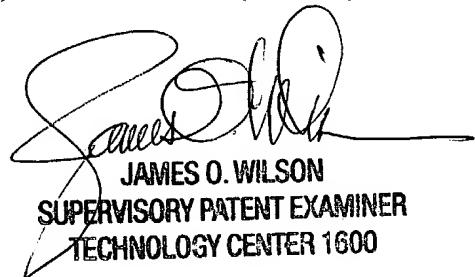
1. Claims 1-15, 31 and 32 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



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